Rec'd
11-13-2003

NOV 1 4 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Digoxin Assay for Bayer ADVIA® Integrated Modular System (IMS)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033007

1. Intended Use

The ADVIA IMS® Digoxin method is for *in vitro* diagnostic use to quantitatively measure digoxin, a cardioactive drug, in human serum. Measurements obtained are used as an aid in the diagnosis of digoxin overdose and in monitoring therapeutic levels of digoxin to ensure appropriate therapy.

2. Predicate Device

Product Name	Reagents & Calibrators	Controls
Immuno 1 Digoxin Assay	K912616	K885226

3. Device / Method

Product Name
ADVIA IMS Digoxin Assay

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
0.75	6.0
1.9	5.9
3.3	3.8

Immuno 1	
Level (ng/mL)	Total CV(%)
0.7	8.2
2.2	4.2
3.4	3.6

Correlation (Y= ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	72	Y=1.017X+0.055	0.265	0.985	0.04 to 4.73

Interfering Substances

Interferant	Spiked Concentration (mg/dL)	Expected Concentration (ng/mL)	Observed Concentration (ng/mL)	% Deviation
Bilirubin	25.0	0.77	0.80	3.6
		2.03	2.05	0.7
		3.44	3.67	6.2
Triglycerides	1000.0	0.73	0.72	-1.7
		1.87	1.88	0.1
		3.21	3.30	3.0
Hemoglobin	1000.0	0.67	0.64	-4.0
		1.82	1.71	-6.9
		3.18	3.07	-3.6

Analytical Range
0.04 – 6 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.04	0.04

Table of Similarities and Differences between IMS Digoxin and Immuno 1 Digoxin assays:

Package Insert Sections	***ADVIA IMS Digoxin assay***	Bayer Immuno 1 Digoxin assay *(predicate device)*
Intended Use	Similar	Similar
Summary	Similar	Similar
Principle	Heterogeneous Competitive Magnetic Separation Assay	Heterogeneous Competitive Magnetic Separation Assay
Reagents	Two liquid reagents contained in system specific packaging	Two liquid reagents contained in system specific packaging
Storage	2-8 °C	2-8 °C
Stability	Similar	Similar
Precautions	Similar	Similar
Indications of Deterioration	Similar	Similar
Performance Characteristics	Similar	Similar
Limitations	Similar	Similar
Parameters	Similar	Similar

9/24/03
Date

Kenneth T. Edds
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer HealthCare
511 Benedict Avenue
Tarrytown, New York 10591-5097

NOV 1 4 2003

Re: k033007
Trade/Device Name: Digoxin Assay on the Bayer ADVIA IMS® Analyzer
Regulation Number: 21 CFR § 862.3320
Regulation Name: Digoxin Test System
Regulatory Class: II
Product Code: KXT
Dated: September 26, 2003
Received: September 26, 2003

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Rec'd 11-13-200

510(k) Number: K033007

Device Name: Digoxin Assay for the Advia IMS

Indications for Use:

The *Bayer ADVIA® IMS™* Digoxin assay is for *in vitro* diagnostic use to quantitatively measure digoxin, a cardioactive drug, in human serum. Measurements obtained are used as an aid in the diagnosis of digoxin overdose and in monitoring therapeutic levels of digoxin to ensure appropriate therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033007

Prescription Use ✓ OR Over-The-CounterUse _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)